International justice: Brazil's last chance against COVID-19

David Andrew Taylor
Partner
Almeida Advogados

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As one of the countries hardest hit by COVID-19, Brazil's recovery hinges on the success of its vaccination program. David Andrew Taylor reports

IN BRIEF

- In spite of the measures passed in Brazil to attempt to mitigate the impact of the coronavirus pandemic, the country has continued to struggle due to the scale and number of obstacles hindering its recovery.
- It is vital that the immunisation program currently being rolled out succeeds.

These are uniquely trying times as the world collectively responds to what is now the second wave of the pandemic of the novel virus SARS-CoV-2 and its resulting disease COVID-19. According to the Weekly Epidemiological Update of the World Health Organization (WHO) of 23 February 2021, there are now over 110.7m reported cases and over 2.4m deaths globally to date. And there are now more transmissible variants of SARS-CoV-2, such as VOC-202012/01, of which variant 94 countries (including Brazil as of 31 December 2020) now report imported cases or community transmission.

Worst case scenario

The general constant fear about Brazil, based on the pandemic progression model, is that widespread COVID-19 transmission, in addition to ever-increasing mortality numbers, will result in critical overload of the public and private healthcare system. This is now the present situation in Manaus (the capital of the state of Amazonas) for example, where the hospital situation has been totally overwhelmed. In Rio de Janeiro, as reported on 25 January 2021, 90% of the intensive care unit beds are occupied with COVID-19 patients, as are 75% of its infirmaries. On 30 January 2021, the state of São Paulo registered 544 COVID-19 new cases and 9.6 new deaths in every hour.

Brazil—with 10,551,259 total COVID-19 cases and 254,942 total deaths (second to the US in number) as of 1 March 2021—had initially braced itself for the worst case scenario, taking action in similar fashion to other countries. On 22 January 2020, the Brazilian Ministry of Health (MOH) COVID-19 Public Health Emergency Centre of Operations was established, and published a national contingency plan. On 3 February 2020, Brazil declared a public health state of emergency of national importance relative to the disease, and on 6 February 2020, Federal Law No 13.979 was passed to implement the same, directing that all Brazilian citizens cooperate with the public health authorities, avoid close contact with those who are infected, and avoid circulation in so-called contamination regions. Furthermore, all federal, state, district, and municipal public health authorities were obligated to share essential information and identify those suspected of being infected and curtail COVID-19 propagation by their isolation and quarantine, which directive would also apply to the private sector when so instructed.

In spite of all this regulation, and the other emergency regulations that Brazil implemented since the onset of the pandemic, its supermarkets, shopping malls and retail stores are fully open. The beaches and their kiosks and restaurants are being frequented as normal, and public transportation restriction directives are being only very loosely adhered to.

According to the 2019 Brazilian Institute of Geography and Statistics (IBGE) statistics, 13.5 million of Brazil's 213 million total population live in extreme poverty. And, according to the World Bank's collection of development indicators, in 2018 16.2% of Brazil's urban population lived in overcrowded and unsanitary favelas (slums).

It is against this backdrop that Brazil's attempts to mitigate the impact of the pandemic must necessarily be measured and understood.

The vaccination campaign

With respect to Brazil, its first edition national plan for the vaccination against COVID-19 was only elaborated in formal manner on 16 December 2020. In accordance with the national plan, negotiations are now presently underway, as a result of which close to 350 million doses are expected to become available within 2021 (markedly short at double dosage).

The co-invented AstraZeneca/University of Oxford COVID-19 vaccine Covishield is the main vaccine being held forth under this first edition of Brazil's national plan. Covishield is a replication-deficient chimpanzee viral vector vaccine, with Brazil and UK-conducted Phase III trials. As published on 8 December 2020 in *The Lancet*, the pooled results were 70.4% efficacy. Its storage and transport are 2–8 degrees Celsius (normal refrigeration temperature).

On 26 June 2020, the Brazilian MOH appointed its affiliated Oswaldo Cruz Foundation (Fiocruz) for absorption of the Covishield technology and local production. As result of a 8 September 2020 Technological Order Agreement, an estimated 100.4 million doses of the vaccine are anticipated by July 2021 and 110 million doses of finished national product between August and December 2021.

In follow up and in anticipation of the national plan and its implementation, a number of non-binding memorandums of understanding were also signed by the Brazilian federal government, including with Pfizer-BioNTech (mRNA-based; 70 million doses total, 8.5 million by June 2021) and Janssen Pharmaceutical Companies (adenoviral vaccine; 38 million doses total, 3 million by the second quarter of 2021).

On 25 September 2020, Brazil executed an optional purchase arrangement commitment agreement with the Covax initiative as a self-financing participant in its facility purchasing pool. On 9 October 2020, USD$148m was made in pro-rata upfront payment by Brazil, securing 42.5 million doses (at USD$3.10/dose), the exact manufacturers and delivery calendar to be determined.

Following publication of the national plan, on 7 January 2021, the Brazilian federal government contracted with the State of São Paulo Secretary of Health-linked Instituto Butantan for 46 million doses of China's Sinovac Biotech-produced CoronaVac, with an option for an additional 54 million, the first 8.7 million to be delivered by 31 January 2021 (6 million imported and 2.7 million national product) and the final doses (in national product) to be received by 30 April 2021.

CoronaVac's inactivated pathogen vaccine's Phase III human clinical trials are being conducted in China, Turkey, Brazil, Indonesia, and Chile. As was formally divulged on 12

January 2021, its overall Brazil study efficacy is 50.38%. Priced at USD$10.30/dose, its storage and transport temperatures are that of normal refrigeration temperature.

On 17 January 2021, the Brazilian Health Regulatory Agency (Anvisa) established the temporary authorisation for emergency use, on an experimental basis, of CoronaVac and Covishield, manufactured by Serum Institute of India.

On 19 January 2021, the Brazilian federal government formally initiated its vaccination rollout program with 6 million doses of CoronaVac, the same to be initially dedicated, it was announced, towards the vaccination of the indigenous population and healthcare professionals attending to them on a priority population basis. And, on 22 January 2021, 2 million doses of Covishield were shipped from India to Brazil.

All this being told, it truly remains to be seen how well Brazil's attempts at containing COVID-19 transmission, morbidity and mortality will actually be effective through its vaccination campaign.

Bumps in the road

According to Brazil's MOH, Brazil's national immunisation program is the largest public immunisation program in the world. It distributes hundreds of millions of doses of 19 different types of vaccines yearly through a network of 37,000 public health system vaccination posts throughout 5,570 Brazilian municipalities. Anvisa is responsible for inventory control and distribution nationwide by plane, train (albeit limited), refrigerated truck and boat transport. Each Brazilian state has its own regional Anvisa-determined refrigeration units. Transport out is typically prioritised earliest-expiry-first-out (EEFO).

There are, however, considerable operational and other challenges to be taken into account.

According to FGV Transport-cited statistics, Brazil has 1.72 million kilometres of roadway, of which only 214,000 kilometres are paved. The majority of highways are under public oversight, 66% of which are to be considered to be of reasonable, bad or terrible condition based on a recent National Transport Confederation-CNT study.

Hundreds of millions of COVID-19 vaccine vials will need to be transported in Brazil during the course of 2021 and, depending on the temperature requirements of the particular vaccine, may require in addition very many thousands of refrigerated storage units and trucks, portable batteries, generators, and refrigerators.

As noted in the first edition of Brazil's national plan, Pfizer-BioNTech, a double dose vaccine with an efficacy rate of approximately 95%, was in Phase III clinical testing but, like Moderna, from the transport and storage perspective presented considerable operational obstacle for reason of its ultra-low temperature (ULT) requirement. Janssen is 85% effective in preventing severe disease, is single dose, and is compatible with standard vaccine transport and storage. But the strategy regarding use of this vaccine is only to be presented in the national plan's second edition.

Both the to-date emergency use-only Brazil-approved double-dose AstraZeneca and CoronaVac vaccines now being exclusively applied in Brazil rely on a cold chain transport and storage infrastructure that is of typical refrigerator temperature. But even the standard vaccine cold chain storage environments and minimised time-out-of-refrigeration (TOR) risks to these two vaccines are not guaranteed to be 100% constant due to the irregular electricity supply and the electricity outages that occasionally seriously affect the north and northeast of the country. Take, for example, the electric energy blackout that affected 90% of the state of Amapá in the north of Brazil for most of the month of November 2020, when a substation energy generator caught fire and transmission lines and hydroelectric plants shut down automatically and substation supply and backup power transformers were 'unavailable.'

Vial, syringe and needle supply and the supply of other COVID-19 vaccine-related resources is also a major concern, subject to local plant production as well as international capacity. At present there are only four syringe manufacturers in Brazil and one needle manufacturer. Current syringe production capacity in Brazil is 10 million/month. On 16 December 2020, Brazil's MOH sought to purchase 331 million syringes via public electronic bid, but its reference prices were too low and only 7.9 million were obtained. On 14 January 2021, the Brazilian MOH formally stated to the Brazilian Federal Supreme Court that seven Brazilian states do not have sufficient syringe stock to meet initial demand going into this year. There needs to be a Brazilian pharmaceutical industry wartime-like organised footing to produce these basic needs (as likewise such organisation is needed to produce the necessary precursors and chemicals for local, quality, standard process vaccine manufacture and production).

There is also the challenge of equitable distribution to be faced. In the geographic locations of proven community transmission in Brazil, only patients presenting severe symptoms have been tested due to test kit shortage and unreliability and most favela communities have needed to self-organise—including via resident drug lord intervention—so as to attempt social isolation and the dissemination of related food, hygiene and information in order to prevent the spread of COVID-19 among themselves. Vulnerability also clearly relates to vaccine application in the many unprotected favela populations.

Downplaying is deadly

Rapid mass vaccination is clearly vital, but the vaccine rollout in Brazil has been chaotic so far. As observed by Bloomberg's Brazil Country Chief on 28 January 2021, '[a]lmost two weeks after national vaccinations began, Brazil is still not reporting consolidated figures. Officials say there are technical issues preventing the Health Ministry from publishing data it receives from local governments.'

Most significantly impacting on the immunisation effort has been the widely-known politicisation preceding it, noted in the Human Rights Watch World Report as, inter alia, including President Bolsonaro's downplaying of the 'little flu,' dissemination of misleading information and blocking of states from imposing social distancing rules. Brazilian public sentiment has, resultantly, been mixed regarding the seriousness of the disease. Without public health expert-led open and transparent communication, and cross-governmental collaboration, Brazil's management of the pandemic to date is considered the world's worst out of 98 countries, as ranked by the Australian thinktank Lowy Institute.

At the present time, only the two vaccines approved on an emergency use basis in Brazil are being administered, and supply is limited. The natural expectation is that as time goes by, further vaccines will be approved and product capacity and supply expanded, with gradual wind-down after general public open access to vaccines. To turn this expectation into reality, there must be full operational capacity and rigid coherence and alignment to the vaccine program. Mass testing and contact tracing is not viable and has not been implemented in Brazil, nor have full-hearted lockdowns been implemented.

With immunity to the virus of around 75% of the population (herd effect), there are fewer people available to become infected and the infection rate eventually stops increasing and dies down. The new mutations of COVID-19 however are increasingly contagious, so transmission is increasing rapidly, and mutations increase with virus spread. For Brazil, the real success of its immunisation vaccine program is crucial. The recovery of the nation depends on it. **NLJ**

David Andrew Taylor, partner, Almeida Advogados, Brazil. To read an extended version of this article please visit his biography page at *www.almeidalaw.com.br*.